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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/673,121	09/26/2003	Shripad S. Bhagwat	10624-133-999	1280

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EXAMINER	
KIM, JENNIFER M	
ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 09/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/673,121	BHAGWAT ET AL.	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 June 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35-41,47-50, 55-61,67-69,75-78,80-82 and 86-90* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35-41,47-50,55-61,67-69,75-78,80-82 and 86-90* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/9/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

The amendment filed June 9, 2005 have been received and entered into the application.

It is noted that claims are examined only to the extent of Applicants' election of species of disorder of treating **cancer.**

Action Summary

1. The rejection of claims 22-24, 50-69, 75-84, 86 and 87 rejected under 35 U.S.C. 112, first paragraph regarding the claims drawn to "prevention" is hereby expressly withdrawn in view Applicant's amendment. However, the claims drawn to treating "cancer" or specified "cancer" drawn to claims 35-41, 4750, 55-61, 67-69, 75-78, 80-82, 86 and 87 is being maintained and modified version of the rejection among with newly added claims 88-90 is included in this Office Action.

The rejection of claims 22-24, 31-69, 75-84, 86 and 87 under 35 U.S.C. 102(e) as being anticipated by Reich et al. (U.S.2002/0161022) is hereby expressly withdrawn in view of Applicant's amendment.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 35-41, 47-69, 75-84 and 86 -90 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the "inhibition of JNK", does not reasonably provide enablement for the "treatment of cancer (i.e. colon, rectum, prostate, liver, lung, bronchus, pancreas, brain, head, neck, stomach, skin, kidney, cervix, blood, larynx, esophagus, mouth, pharynx, urinary bladder, ovary, or uterine).". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

4. Enablement is considered in view of the Wands factors (MPEP 2164.01(a)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, predictability of the prior art, state of the prior art and the amount of experimentation necessary. All of the **Wands factors** have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the Invention: All of the rejected claims are drawn to a method of treating cancer including colon, rectum, prostate, liver, lung, bronchus, pancreas, brain, head, neck, stomach, skin, kidney, cervix, blood, larynx, esophagus, mouth, pharynx, urinary bladder, ovary, or uterine, responsive to JNK inhibition in a subject with an effective amounts of compound of structure set forth in claims 35, 39-41, 47, 48, 55, 59-61, 67, 68 and 78. The nature of the invention is extremely complex in that it encompasses the actual treatment of a cell

proliferation disorder (i.e. cancer of colon, rectum, prostate, liver, lung, bronchus, pancreas, brain, head, neck, stomach, skin, kidney, cervix, blood, larynx, esophagus, mouth, pharynx, urinary bladder, ovary, or uterine) such that the subject treated with above compounds does not contract the specified cancer.

Breath of the Claims: The complex of nature of the claims greatly exacerbated by breath of the claims. The claims encompass treatment of cancer, a complex cell proliferation disorder responsive to JNK inhibition in humans which has potentially many different causes (i.e. many different mutations or combination of mutations). Each of which may or may not be addressed by the administration of the claimed compounds.

Guidance of the Specification: The guidance given by the specification as to how one would administered the claimed compounds to a subject in order to actually treatment of individual specified cancer is minimal. All of the guidance provided by the specification is directed towards inhibition of JNK pathway in vitro rather than actual treatment of cancer in vivo.

Working Examples: All of the working examples provided by the specification are directed toward the JNK inhibition in vitro rather than treatment of cancer in vivo.

State of the Art: While the state of the art is relatively high with regard to treatment of cell proliferation disorder with specific active agent (i.e. breast cancer with tamoxifen), the state of the art with regard treatment of various cancer including colon, rectum, prostate, liver, lung, bronchus, pancreas, brain,

head, neck, stomach, skin, kidney, cervix, blood, larynx, esophagus, mouth, pharynx, urinary bladder, ovary, or uterine, with a single compound is underdeveloped. In particular, there do not appear to be any examples or teachings in the prior art wherein a compound similar to the claimed compounds was administered to a subject in vivo data to treat all of cancer including colon, rectum, prostate, liver, lung, bronchus, pancreas, brain, head, neck, stomach, skin, kidney, cervix, blood, larynx, esophagus, mouth, pharynx, urinary bladder, ovary, or uterine.

Predictability of the Art: The lack of significant guidance from the specification or prior art with regard to the actual treatment of cancer in a human subject with the claimed compounds makes practicing the claimed invention unpredictable in terms of actual treatment of cancer.

The amount of Experimentation Necessary: In order to practice claimed invention, one of skilled in the art would have to first envision a combination of appropriate pharmaceutical carrier, compound dosage, duration of treatment, route of administration, etc. and appropriate animal model system for one of the claimed compounds and test the combination in the model system to determine whether or not the combination is effective for the treatment of any cancer. If unsuccessful, which is likely given the lack of significant guidance from the specification or prior art regard to treatment of cancer in vivo data with any compound, one of skill in the art would have to then either envision a modification of the first combination of pharmaceutical compound, compound dosage,

duration of treatment, route of administration, etc. and appropriate animal model system, or envision an entirely new combination of the above, and test the system again. If again unsuccessful, which is likely given the lack of significant guidance form the specification of prior art regarding actual treatment of cancer in vivo with any compound, the entire, unpredictable process would have to be repeated until successful. Therefore, it would require undue, unpredictable experimentation to practice the claimed invention to treat cancer in a subject by administration of one of the claimed compounds.

Therefore, a method of treating cancer colon, rectum, prostate, liver, lung, bronchus, pancreas, brain, head, neck, stomach, skin, kidney, cervix, blood, larynx, esophagus, mouth, pharynx, urinary bladder, ovary, or uterine responsive to JNK inhibition in a subject administering compounds set forth in claims 35, 39-41, 47, 48, 55, 59-61, 67, 68 and 78 is not considered to be enabled by the instant specification.

Response to Arguments

Applicants arguments filed June 9, 2005 have been fully considered but they are not persuasive. Applicants argue that the present specification teaches how to make the compounds recited in the present method claim and how to prepare the compounds for pharmaceutical administration and that numerous animal models known in the art for the various types of cancer. This is not persuasive because to the extent that the claim is directed to a method of treating cancer in vivo, which is highly speculative, a greater

amount of evidence is required to show its operability in humans. It is to be noted that no vivo data has been presented to establish that applicant's compounds would act in the manner claimed (inhibition of JNK) as they related to the actual treatment of cancer in general. Further, Applicants' data has been reviewed but does not establish a correlation between in-vitro tests performed and the use of the applicants active agents in-vivo.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax

phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sreenivasan Padmanabhan
Supervisory Examiner
Art Unit 1617

Jmk
September 6, 2005